K093643

1.4 510(k) Summary of Safety and Effectiveness

JUN 2 4 2010

Submitted by:	Herbert Crane Director, Global Regulatory Affairs
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Date of Submission:	March 29, 2010
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Trade or Proprietary or Model Name:	Multi-Unit Abutments for Straumann and AstraTech Implant Systems
Legally Marketed Device(s):	Multi-Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems (K061477) NobelActive Multi Unit Abutments (K072570) OsseoSpeed Profile Systems (K080156) SLActive Implants (K053088) P.004 Implants (K062129)

Device Description:
Nobel Biocare's Multi-Unit Abutments for Straumann and AstraTech Implant Systems are endosseous dental implant abutments. The Nobel Biocare Multi-Unit Abutments for Straumann and AstraTech Implant Systems attach directly to endosseous dental implants and provides a platform for restoration.

Nobel Biocare's Multi-Unit Abutments for Straumann and AstraTech Implant Systems are made entirely of titanium/vanadium alloy.

Indications for Use:
Nobel Biocare's Multi-Unit Abutments for Straumann and AstraTech Implant Systems are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

The abutments fit the following implant platforms.

- Straumann - Octagon Regular Neck 4.8
- Straumann - Octagon Wide Neck 6.5
- Straumann - Bone Level NC 3.3
- Straumann - Bone Level RC 4.1/4.8
- Astra Tech - OsseoSpeed 3.0 (yellow)
- Astra Tech - OsseoSpeed 3.5/4.0 (Aqua)
- Astra Tech - OsseoSpeed 4.5/5.0 (Lilac)

Summary of testing to demonstrate safety and effectiveness
Nobel Biocare's Multi-Unit Abutments for Straumann and AstraTech Implant Systems were analyzed to identify worst-case test samples. These worst-case test samples were subject to fatigue testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the abutments are substantially equivalent to the identified predicates.

Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE	PREDICATE	PREDICATE
	Multi-Unit Abutment for Straumann and Astra Tech Implant Systems	Multi-Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems (K061477)	NobelActive Multi Unit Abutments (K072570)	OsseoSpeed Profile Systems (K080156)	SLActive Implants (K053088)	P.004 Implants (K062129)
Anatomical Site	**- Oral Cavity**	- Oral Cavity	- Oral Cavity	- Oral Cavity	- Oral Cavity	- Oral Cavity
Material	**- Titanium Alloy**	- Titanium - Titanium Alloy	- Titanium Alloy	- Titanium	- Titanium	- Titanium
Platform	**- Straumann Octagon RN 4.8, WN 6.5** **- Straumann Bone Level NC 3.3 Bone Level RC 4.1/4.8** **- Astra Tech OsseoSpeed 3.0 (yellow) 3.5/4.0 (Aqua) 4.5/5.0 (Lilac)**	- Astra Tech 3.5, 4.0, 4.5, 5.0 mm - Camlog 3.3, 3.8, 4.3, 5.0, 6.0 mm - Ankylos 3.5, 4.5, 5.5, 7.0 mm	- NobelActive	- Astra Tech OsseoSpeed 3.0 (yellow) 3.5/4.0 (Aqua) 4.5/5.0 (Lilac)	- Straumann Octagon RN 4.8, WN 6.5	- Straumann Bone Level NC 3.3 Bone Level RC 4.1/4.8
Abutment Height	**- 1.5, 2.5, 3.5, 4.5**	- 1.5 mm	- 1.5, 2.5, 3.5, 4.5	N/A	N/A	N/A
Abutment Angulation	**- 0, 17, 30 deg**	- 0 deg	- 0, 17, 30 deg	- 0, 20 deg	- 0, 15 deg	- 0, 15 deg

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Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE	PREDICATE	PREDICATE
	Multi-Unit Abutment for Straumann and Astra Tech Implant Systems	Multi-Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems (K061477)	NobelActive Multi Unit Abutments (K072570)	OsseoSpeed Profile Systems (K080156)	SLActive Implants (K053088)	P.004 Implants (K062129)
Interface Design	- **Internal Morse taper with hexagonal index** - **Internal Morse taper with octagonal index** - **Internal Morse taper with slotted index**	- Astra Tech Internal connection, double hex - Camlog Internal connection, three symmetrical arranged internal groves - Ankylos Internal conical connection	- Internal Morse taper with hexagonal index	- Internal Morse taper with hexagonal index	- Internal Morse taper with octagonal index	- Internal Morse taper with slotted index
Indications for Use	**Nobel Biocare's Multi-Unit Abutments for Straumann and AstraTech Implant Systems are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic**	Nobel Biocare's Multi-Unit Abutment is a premanufactured prosthetic component intended for use as an aid in prosthetic rehabilitation. Nobel Biocare's Multi-Unit Abutments fit the following endosseous implants:	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	* See Below	* See Below	* See Below

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Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	CANDIDATE	PREDICATE	PREDICATE	PREDICATE	PREDICATE	PREDICATE
	Multi-Unit Abutment for Straumann and Astra Tech Implant Systems	Multi-Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems (K061477)	NobelActive Multi Unit Abutments (K072570)	OsseoSpeed Profile Systems (K080156)	SLActive Implants (K053088)	P.004 Implants (K062129)
	rehabilitation. **The abutments fit the following implant platforms.** - **Straumann - Octagon Regular Neck 4.8** - **Straumann - Octagon Wide Neck 6.5** - **Straumann - Bone Level NC 3.3** - **Straumann - Bone Level RC 4.1/4.8** - **Astra Tech - OsseoSpeed 3.0 (yellow)** - **Astra Tech - OsseoSpeed 3.5/4.0 (Aqua)** - **Astra Tech - OsseoSpeed 4.5/5.0 (Lilac)**	- AstraTech 3.5, 4.0, 4.5, 5.0 mm - Camlog 3.3, 3.8, 4.3, 5.0, 6.0 mm - Ankylos 3.5, 4.5, 5.5, 7.0 mm				

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Substantial Equivalence Comparison to Predicate Devices

OsseoSpeed Profile Systems (K080156), Indication for Use

OsseoSpeed Profile is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla. The device may be used equally well in single-stage or two-stage surgical procedure. It is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

The fluoride-modified surface, though having a fluoride ion level far below that needed for caries prevention in teeth, provides a favorable substrate for bone attachment and osseointegration. OsseoSpeed Profile is especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective. Because initial stability may be difficult to obtain in Type IV bone, immediate loading of single tooth restorations may not be appropriate in such situations.

SLActive Implants (K053088), Indications for Use

SLActive implants are for single-stage or two-stage surgical procedures. SLActive implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used in immediately loaded cases.

P.004 Implants (K062129), Indications for Use

The P.004 Implants are intended for immediate, delayed or conventional placement in the maxilla ond/or mandibular arches to support crowns bridges or overdentures in edentulous or partially edentulous patients.

They are intended for immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used.

Abutments are intended to be placeddental implants to provide support for prosthetic reconstructions such as crowns or bridges. Meso abutments are indicated for cemented restorations particularly in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nobel Biocare AB
C/O Mr. Herbert Crane
Director, Global Regulatory Affairs
Nobel Biocare USA LLC
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JUN 24 2010

Re: K093643
Trade/Device Name: Multi-Unit Abutments for Straumann and Astra Tech Implant Systems
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseuos Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 23, 2010
Received: June 24, 2010

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093643

1.3 Indications for Use

510(k) Number (if known): K093643

Device Name: Multi-Unit Abutments for Straumann and Astra Tech Implant Systems

Indications For Use:

The Multi-Unit Abutments for Straumann and Astra Tech Implant Systems are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093643